Volume VI Issue 40
February 2016

POSTSCRIPTS

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Official publication of the American Medical Writers Association Pacific Southwest Chapter

Postscripts
February 2016
AMWA Pacific Southwest Chapter

POSTSCRIPTS

AIMS AND SCOPE

Postscripts is the official publication of American Medical Writers Association (AMWA) Pacific Southwest chapter. It publishes news, notices, job postings, and articles of interest in all areas of medical and scientific writing and communications. The scope covers clinical and regulatory writing, scientific writing, publication planning, continuing medical education (CME) and physician/patient education, social media, current regulations, ethical issues, medical writing training and certification, and good writing techniques.

MISSION STATEMENT

The mission of *Postscripts* is to facilitate the professional development of medical writers and serve as a tool to advance networking and mentoring opportunities among all members. Towards this mission, *Postscripts* publishes significant advances in issues, regulations and practice of medical writing and communications; skills and language; summaries and reports of meetings and symposia; and, book and journal summaries. Additionally, to promote career and networking needs of the members, *Postscripts* includes news and event notices covering AMWA Pacific Southwest Chapter activities.

SUBSCRIPTION: *Postscripts* is published monthly except in January and July. The magazine is available as open access publication and is currently distributed online only.

INSTRUCTION FOR CONTRIBUTORS: We consider articles on any topic of interest to our membership. It is helpful to look at the past December issues for year-end table of contents, and browse past issues for style and type of articles published. We welcome contributions from AMWA members. Non-member contributions are generally by invitation by the Editor or any member of the Chapter's Board. Detailed instructions are provided in the December 2015 issue, *Postscripts* 2015;5(39):204.

ADVERTISING: *Postscripts* is an advertising-free magazine. However, articles describing products and services relevant to medical writers, editors and communicators may be considered or solicited. As a service to our members, they may submit advertisements for their services or products for free. Please contact the Editor.

WEBSITES:

Chapter website: http:// www.amwa-pacsw.org
AMWA website: http://www.amwa.org
Postscripts: http://issuu.com/postscripts

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In this issue. . .

COVER:
"School Sign". By Emily Roesly (mesantic), Nuclear, Jersey. Emily's webpage: www.emilysimagery.com
Picture source: http://www.morguefile.com/archive/display/994221.

From the President's Desk

First of all, let me say that I'm honored to become President of this thriving chapter whose growth and success is due to its enthusiastic members and leadership, and especially to the amazing efforts of the current Past President, Donna Simcoe. As everyone knows, we were very lucky to have Donna as our leader for the past two years, and we're lucky to have her continuing in the chapter leadership. We're also very grateful that she will continue to lead the highly appreciated monthly chapter teleconferences at noon on the first Friday of the month.

Thanks also to Ajay Malik for his devotion to the award-winning Postscripts, and for asking me to continue the tradition of writing an introduction. Our February issue leads with Dimity Budker's rules of good scientific writing, plus Dikran Toroser's column on authorship guidelines from the AMA Manual of Style and the GPP3 guidelines. It also includes an "infographic on infographics," Lycely Sepulveda's article on developing figures and illustrations; an explanation of the new world of pet participation in clinical trials by Rebecca Anderson; our recurring column on FDA updates from Kokil Tandon; some suggestions on using the KonMari method of home organization by April Reynolds; and a review of trends in precision medicine from Kokil Tandon. In addition, we have reviews of the January chapter events in Northridge and the Sanford Burnham Prebys Institute by Eileen Lai-Hoshino and Asoka Banno.

A note about our chapter communications – we are working on replacing our current email system, which had the awkward habit of dropping members without notice to us. Our apologies for that, and be sure to let us know if this seems to be happening to you.

Please keep April 16 on your calendar for the AMWA Pacific Coast Conference in downtown San Francisco. It is being planned by the Northern California chapter as a one day event at the Park Central Hotel; more details to come soon. As our save the date email has mentioned, it will include workshops, open sessions, and networking events, plus the chance to party in one of the world's most beautiful cities.

I look forward to meeting as many of our members as possible in the coming months, and please do drop me a line at president@amwa-pacsw.org if you have any questions or comments, or just want to say hi. Have a great month everyone.

Susan

Susan Vintilla-Friedman, MWC
President, AMWA Pacific Southwest Chapter

Background image by Sandrinja via morguefiles. Image URL: http://mrg.bz/qe6UMN

EDITOR'S desk

Gavel, Thin Mints and Goals

Welcome to the first issue of Postscripts for 2016.

Passing the Gavel

The AMWA Pacific Southwest Chapter begins the year with the changing of the guard. During the last Chapter meeting in Simi Valley on January 16th, the outgoing president, Donna Simcoe, presented the official presidential gavel to Susan Vintilla-Friedman marking the beginning of Susan's term as the new Chapter President (see page 6). *Symbolically, there was no better place to celebrate this transition than in the shadow of another great president, Ronald Reagan, whose library was just 20 minutes away on a hill to the west.*

Enriching Members' Experience

We have been fortunate to have Donna as our president during the last 2 years. She helped grow opportunities for peer-to-peer interactions between medical writers in our region by developing new programs and expanding existing ones. She started the monthly chapter teleconferences (where many non-members have called in to test the waters), increased the frequency of happy hours, represented medical writing community at local universities' career forums and brought in new speakers for an ever-increasing number of events. Last year, over 500 attendees came to one or more of these events (*Postscripts*, Dec 2015, page 202), and many (who were not AMWA members) decided to join AMWA.

Donna, a ranking member of the International Society for Medical Publication Professionals (ISMPP) kept us abreast with the latest developments in the scientific research publishing and the publication planning world. With the passing of the gavel to Susan Vintilla-Friedman, our Chapter remains in very good hands. Susan adds new perspective to the Chapter. She has been on various educational committees at Drug Information Association (DIA) and AMWA National. Meanwhile, Donna will continue to be engaged with our chapter as the immediate Past President.

So we can report that the State of the Chapter is strong and thriving as we continue our tradition of providing educational and networking opportunities for medical writers in the Pacific Southwest region of the United States.

Thin Mints® and New Year Resolutions

January is also the month of another American tradition, the Girl Scout Cookies. These yellow, green, pink or purple little boxes are the sign of joy and excitement. The Thin Mints®, Samoas®, Tagalongs®, Trefoils® or Savannah Smiles® are more than irresistible, delightful flavors and smiles, they are reminders of 5 skills (listed on the side of each box) that girl scouts strive for:

1. Goal Setting
2. Decision Making
3. Money Management
4. People Skills
5. Business Ethics

These are translatable skills for the medical writer world—what fun it is to enjoy these delightful cookie flavors and be motivated to add these skills to the New Year resolutions list!

Becoming a Better Writer

My top resolution for the year remains becoming a better writer and editor with each passing month and each passing year. Fortunately, there are several tools available to work towards this goal (Decision Making): planning to attend local meetings and events organized or sponsored by our Chapter, San Diego Regulatory Affairs Network, and other local organizations in your area; attending 1 or more national level meeting (AMWA, ISMPP and DIA); working towards AMWA workshops/certificates; or thinking about certifications (MWC™, CMPP®, RAC® and ELS®) are some of the ways to achieve this goal. Browsing the pages of *Postscripts* and reaching out to established members for advice, mentorship (see page 20 in this issue) and guidance are other effective ways towards developing skills as a "better" writer.

Common Rules of Good Scientific Writing

Becoming a better writer starts with knowing the "obvious". On page 7 of this issue, we reprint *Common Rules of Good Scientific Writing*[1] by Dmitry Budker (Professor of Physics at UC Berkeley). His advice on writing is part common-sense part re-educating what medical writers know all along. Here are a few:

- "When in doubt--cross it out."

[1]Budker D. Some rules of good scientific writing. arXiv:physics/0608246

- "The reader does not know what comes next." (ie, we must build a better story)
- "Avoid colloquial terms." (ie, let the jargon stay within your shop)
- "Question each and every statement."
- "Read the final (draft of) manuscript." (self-editing is as important as writing)

The best advice, I felt, was “If you can abstain from writing – do not write!” Or, do not write a paragraph where a sentence would do. This is only possible when a writer reads (and re-reads) draft of a document, questions each and every statement, and builds a compelling story.

(See complete list of *Common Rules* on page 7.)

People Skills

The fourth skill, "People Skills" is as critical as writing itself. A medical writer never works in a vacuum. (*Only writers of suspense novels do, who hide out in the villages of Maine or disappear in the great state of Montana, only to emerge with a novel full of characters with complicated lives*.) Medical writers occupy the hub of people connections collaborating with clinical investigators, authors, statisticians, and others in the corporate food chain. The issues of authorships, managing reviews, and managing timelines require more than steam-rolling a project to meet publication goals. However, medical writers can use predefined (written) procedures and published guidelines as tools to manage “people issues”.

In this issue of Postscripts (page 8), Dikran Toroser provides an update on recently updated Good Publication Practice (GPP) guidelines, known as GPP3, and guidance on authorship from the 10th edition of *AMA Manual of Style*. While relying on published guidelines (as indisputable verses from Bible), the human element will continue to remain more challenging than the process of writing itself.

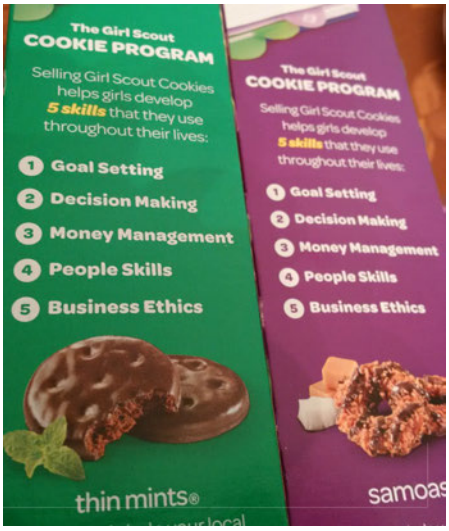
Outside clinical research, the awareness of GPP3 guidelines or best practice guidances[2] from ISMPP or AMWA may be poor in the academia. However, academia is not alien to these issue and the conversation is brewing in the ivory towers too, for example, Budkar and Kimball (Nature. 21 Jan 2016;529:427-428) provide some notes of caution and advice when working with collaborators. Since, medical writers often work with investigators and authors from academia, raising the awareness of codified guidelines (GPP3) and best practices guidelines (from professional medical writing organizations) carry more weight in managing the "people" aspect of developing documents and manuscripts.

A core part of “People Skills” is creating a Feng Sui environment: how to be nice, how to manage expectations, and how to get people to do work on your schedule. A colleague once said, "Take a theater class". *Something to consider this year*.

AMWA Code of Ethics

The last skill evokes "Ethics" that is a must in our profession and is the right thing to do. Awareness of ethical principles help us to be truthful and transparent in our writing – this will not only help our industry be on the right side of the law, but also is the right thing to do. The membership of AMWA requires us to accept 8 principles that constitute the AMWA Code of Ethics[3]. As we embark on another year of working towards *committing to our craft* and *honing our skills*, it is a good time to pause, review and absorb the intent of the AMWA Code of Ethics in our work. The journey to becoming a *better writer* continues.

—Ajay K Malik, PhD



[2]Best practice guideleins at AMWA (www.amwa.org) and ISMPP (www.ismpp.org) websites
[3]AMWA Code of Ethics: http://www.amwa.org/amwa_ethics

AMWA Pacific Southwest Chapter: Changing of Guards

We welcome our new president, Susan Vintilla-Friedman, MWC (right) and thank the outgoing president, Donna Simcoe, MS, MS, CMPP (left) for her service to the Chapter. See pages 20 and 21 for the event report and pictures.

Picture by Eileen Lai-Hoshino

Letter to the Editor

4 January 2016

Editor, Postscripts
Via email

Dear Editor,

As one year ends and a new one starts, it appears to be a universal habit for all to review and renew, to determine what is useful and what is superfluous, and how best to move ahead to make the new year better.

In the spirit of such contemplation, I would like to thank you, as Editor, and all the contributing authors for providing such a fine journal. Being rather attuned to the responsibilities of an editor, albeit not a managing one who actually gets the journal into the hands of the membership, I want to especially commend you for your work. You are an unsung hero of the American Medical Writers Association (AMWA) and my wish for 2016 is that more members recognize and appreciate the work that you do and that you are blessed with more high-quality submissions than you can use!

I sincerely hope that you will publish my letter.

Kind regards,

MaryAnn Foote, PhD
AMWA Swanberg Winner
AMWA Golden Apple Winner
Former AMWA National President

Editor's Note—
Reprinted from arXiv preprint server with permission from Prof. Dmitry Budker, UC Berkeley.
Read the original version at: http://arxiv.org/abs/physics/0608246v3
Cite as: Budker D. Some rules of good scientific writing. arXiv:physics/0608246
(Version Dated: March 21, 2013)

Some Rules of Good Scientifc Writing

By Dmitry Budker, PhD[1,*]

[1]Department of Physics, University of California, Berkeley, CA 94720-7300

A non-native English speaking physics professor formulates obvious yet useful rules for writing research papers.

PACS numbers: 01.20.+x

I. INTRODUCTION

There are many volumes written about technical writing, and I probably do not have too much original material to add to them. Yet, whenever a student brings me a draft of their first research paper, I invariably see an almost universal set of problems. Some of these probably stem from the way writing is taught at school. As an example, at school we are taught to enrich our writing by avoiding repeating the same term and using synonyms instead. Unfortunately, if one is writing a scientific paper, using different words for the same object could be a disaster.

Hoping that these notes will actually be read, let us, without further ado, present

II. THE RULES

- A wise man said: "If you can abstain from writing – do not write!"
- "When in doubt – cross it out." Try it; it really works miracles!
- The contents of a section should match its title.
- An equation appearing in the text should never be presented without comment, unless it is an intermediate step in a derivation.
- All "letters" (i.e., variables and constants) appearing in equations should be explicitly defined, even if seemingly obvious.
- All references, figures, tables, and equations should be numbered in order of appearance.
- Sentences cannot start with an abbreviation [e.g., Fig. 1 or Eq. (2)], or with "So" or "Also."
- It is usually better to use past indefinite tense, for example "it was found" (as opposed to present or past perfect – "it has or had been found"), unless necessary.
- Saying "This was demonstrated by J. Doe (1905)" is correct, while saying "This was demonstrated in J. Doe (1905)" is not.
- Things to be compared shall be presented in a similar manner (for example, on graphs with the same scale).
- One should avoid self-praise, for example, saying that "interesting results were obtained." It should be up to the reader to praise the work!
- The reader does not know what comes next in the paper; consider what the reader should be thinking as they reach this particular point.
- Avoid colloquial terms, for example, "slam" in "The projectile slams the target."
- Question each and every statement: is it actually correct? Can you defend it?
- This one is a must: read the finished manuscript!

III. CONCLUSION

These rules are quite obvious and "common sense." Yet, formulating them explicitly and keeping them in mind while writing could, hopefully, be useful. It goes without saying, that as with most rules, there may be exceptions. Do we follow our own advice? Judge for yourself by checking out some of the recent published work of our group at http://budker.berkeley.edu/.

Acknowledgment

I am grateful to all of my present and and former students and co-authors, and, particularly, to Derek F. Jackson Kimball (now a Professor at California State University, East Bay) for making these rules so apparent.

* Electronic address: budker@berkeley.edu

AMA-zing Style — the AMA Manual of Style Column

By Dikran Toroser, PhD, CMPP, Amgen Inc., Thousand Oaks, Calif.

Authorship Perspectives from the AMA Manual and GPP3 Guidelines

The AMA manual of style is the industry standard for authors, editors and writers in medical and scientific publishing. Authorship related issues, which can be controversial and sensitive, are immensely important in publication development and are accordingly given significant attention in the AMA manual. This article summarizes aspects of authorship-related information, with a historical perspective, referencing the 10th edition of the AMA manual of style and other important publication guidelines.[1, 2]

The AMA manual summarizes and cites the ICMJE guidelines as a foundation for policies and procedures on authorship. ICMJE guidelines are also reviewed, revised, and updated regularly. The following are some comparisons of authorship related information from the AMA manual and GPP3.

• AMA Manual of Style—10th edition

Authorship Definition and Criteria. According to the ICMJE guidelines, all authors should have participated sufficiently in the work to be able to take public responsibility for the content. Sufficient author participation should include:

i. Substantial contribution to conception and design, or acquisition of data, or analysis and interpretation of the data, and
ii. Drafting the manuscript or revising it critically for important intellectual content
iii. Approval of the version of the manuscript to be submitted/presented and
iv. Agreement to be accountable for all aspects of the work thereby ensuring that questions related to the accuracy or integrity of any part of the work are appropriately resolved

To justify authorship, an author must meet each of the 4 criteria above. However, the term ***substantial contribution*** has not yet been precisely defined. Many journals require attestation, in writing, on how authors qualify for authorship and a description of their contributions to the work.

Guest and Ghost Authors must not be included and should be eliminated from the byline.

Medical Writers. To give proper credit to medical writers and authors' editors, journal editors should require authors to identify all persons who have participated substantially in the writing or editing of the manuscript. Substantial editing or writing assistance should be disclosed at the time of manuscript submission and mentioned in the Acknowledgment.

Number of Authors—a complex history. The number of authors whose names appear in the byline of scientific papers has increased steadily during the second half of the 20th century—often due to multidisciplinary collaborations and multicenter organizations. Authorship inflation has the potential to "*dilute*" the meaning of authorship and represents a dilemma—which authors on the byline containing more than 100 names actually wrote the paper?

In response to this problem, suggestions have often been made (during the 1980s and 1990s) to limit the number of authors listed in the byline and database citations. Interestingly, the present version of the AMA manual of style suggests that setting such author limitations and arbitrary limits "*may interfere with policies to encourage transparency of author contributions and thus are not justified*."

Using the same rationale, MEDLINE/Pubmed removed limits to the number of individual authors' names listed in an article's citation (see detailed MEDLINE field descriptions at: https://www.nlm.nih.gov/bsd/mms/medlineelements.html#au). For full articles, JAMA does not limit author number, as long as each author completes an authorship form indicating specific contributions. For practical reasons (eg, space), the names of authors may be listed at the end of the article or elsewhere within an article instead of in the byline at the beginning.

• GPP3 guidelines

These recently published guidelines focus on the "principles of good publication practice for company-sponsored medical research" and are now endorsed by many medical journals, and contain significant guidance on authorship issues.[2] GPP3 reflects changes in the rapidly evolving medical publications environment—including regarding authorship.

GPP3 contains a useful 10-item summary (the so-called GPP commandments) many of which focus on authorship-related issues (see below.)

Summary of author-related principles of GPP3 for company-sponsored medical research

- *The rights, roles, requirements, and responsibilities of all contributors should be confirmed in writing, ideally at the start of the research, before publication preparation begins.*
- *All authors should have access to relevant aggregated study data and other information required to understand and report research findings.*
- *The authors should take responsibility for the way in which research findings are presented and published, be fully involved at all stages of publication and presentation development, and be willing to take public responsibility for all aspects of the work.*
- *Author lists and contributorship statements should accurately reflect all substantial intellectual contributions to the research, data analyses, and publication or presentation development.*
- *All authors and contributors should disclose any relationships or potential competing interests relating to the research and its publication or presentation.*

Author-number and Order of Authors: Under qualification for authorship, the GPP3 guidelines state: "*Priority should be given to the key contributors who have the necessary background to analyze or interpret the findings*." Additionally, the guidelines state that authorship criteria should be applied ***consistently***. The guidelines further summarize guidance in tabular format regarding number of authors: "*…it would be unusual in biomedical research (with few exceptions) to require >10 authors…Fewer authors are often preferable, and others can be acknowledged…*"

As the GPP3 authors have implied, due to the rapid evolution of the publication field, there will always be "grey areas" which may become clearer with ongoing research into publication practices. With regards to author number considerations, it may be important to refer to both the AMA manual as well as GPP3 for guidance.

See pages 127 to 140 in the AMA Manual of Style 10th edition, ICMJE[1] and GPP3[2] for additional information.

REFERENCES

1. ICMJE authorship criteria. http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html.
2. Battisti et al (2015) Good Publication Practice for Communicating Company-Sponsored Medical Research: GPP3. Ann Intern Med, 163, 461

DIKRAN TOROSER, PhD, CMPP, a member of the AMWA Pacific Southwest chapter, is a regular contributor to the *Postscripts* magazine since 2012. He developed the monthly AMAzing Style column which covers topics from the AMA Manual of Style, and has also written on publication-related topics in these pages. Dikran is currently a Senior Medical Writing Manager at Amgen Inc. in Thousand Oaks, California. He earned his PhD in Biochemistry from Newcastle University (UK), and did his post-doctoral training in biochemical genetics at the John Innes Center of the Cambridge Laboratory (Norwich, UK) and in molecular biology with the USDA. Prior to Amgen, Dikran was on the faculty (research) at the School of Pharmacy at the University of Southern California. He can be reached at dtoroser@amgen.com.

Summary prepared by Lycely Sepulveda, PhD

7

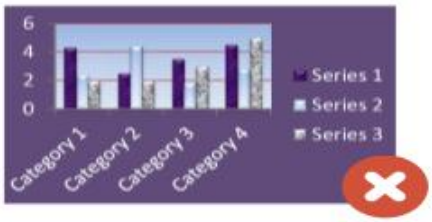
Best Practices for Developing Figures and Illustrations for Publications

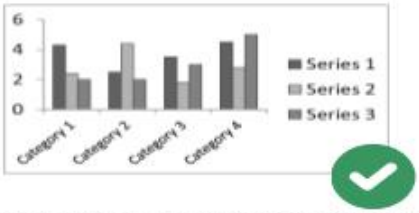
Figures and illustrations help the reader understand and interpret the main information presented in the publication by condensing, visualizing or comparing the most important data.

#1 Target the key message

- Illustrate the most relevant data.
- Use the supplementary data section for other results.

#2 Avoid cluttering

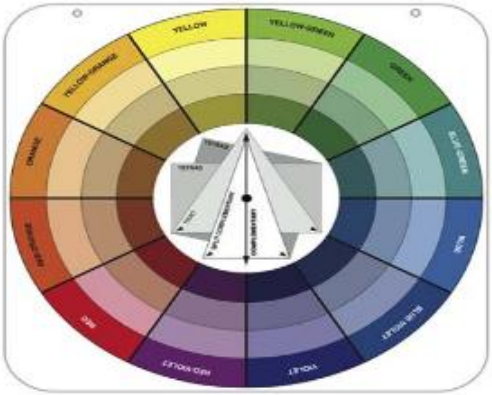




- Remove unnecessary elements from figures.
- Draw attention to important elements when clutter is unavoidable.

#3 Choose colors wisely

- Consult a color wheel to choose balancing colors.
- Avoid unnecessary bright colors.
- Be sensitive to the needs of color blind readers.
- Select darker/grayer colors or pastels for a polished look.



#4 List labels & abbreviations

- Create free-standing figures that could be interpreted without having to read the body of the publication.
- Indicate the attribute being measured and specify the units of measurement.
- Label all axes and state the types of changes being measured (e.i., absolute vs relative changes).
- Specify the meaning of error bars.
- Define all abbreviations.

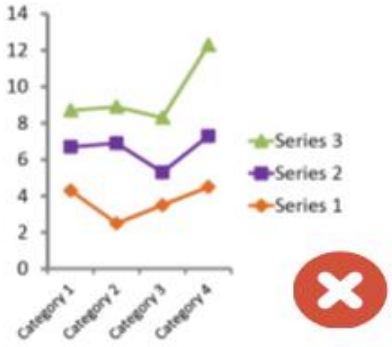
#5 Printer output matters

- Evaluate the readability of the figure printed in both full color and grayscale.
- Use a variety of shapes and line styles that are distinguishable regardless of the format used for viewing.

continued on next page . . .

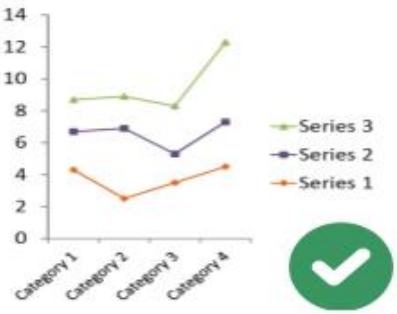
#6 Select good fonts and line weights

- Choose thin, streamlined fonts to achieve a refined look.
- Use a consistent font throughout the figure.
- Emphasize only important information with bold face.
- Select a lighter line weight to avoid visual fatigue.



#7 Use shading for clarity

- Combine shading and color to convey definition.
- Avoid masking political or geographical borders on maps.



References and Credits:
Nawrocki AM. Best Practices for Developing Figures and Illustrations for Publications. Presented at: AMWA Pacific Southwest Chapter Medical Writer's Toolkit Decoded Symposium; September 2015; Thousand Oaks, CA. Summary prepared by Lycely Sepulveda, PhD.
- Color wheel - The Color Wheel Company™.
- Map of Australia - DOI: 10.1111/j.0906–7590.2008.05457.x Reproduced with permission.

LYCELY SEPULVEDA, PhD, has over 20 years of biomedical communication experience in diverse higher education institutions including Stanford University and UC Irvine. After completing her PhD in Microbiology from Michigan State University, Lycely applied her technical communication and management skills to lead multi-site and international Molecular Biology, Infectious Diseases and Biotechnology projects. Lycely plans to leverage her vast research, teaching, regulatory and executive experience to transition into the field of medical writing. Lycely enjoys hiking on the coastal Southern California trails with her family and she can be reached at lycely@gmail.com.

Pet Clinical Trials

By Rebecca J. Anderson, PhD, AMWA Pacific Southwest Chapter Member

As dogs and cats become more like family members, veterinary medicine has also become increasingly human-like. In the latest innovation, veterinarians have joined forces with physicians to conduct drug trials that will benefit both people and pets. We're not talking about your garden variety toxicology testing. In this paradigm shift, pet cats and dogs that have a disease are being recruited just like human experimental subjects.

Now, when Fido is diagnosed, vets may offer him a slot in a drug trial, with the same sort of study protocol as a human trial. Just think about getting Fido's paw print on the consent form. (And changing that eighth grade reading level to dog years.)

It can be a tough sell. Veterinarians must convince Fido's owners to trust the health of their pet to investigators and an experimental drug. (Put "animals" and "experiment" in the same sentence, and you'll probably trigger an anti-vivisection reflex.) But there are benefits. Besides access to a promising drug when a gut-wrenched family learns their beloved pet has an "incurable" disease, expenses are usually covered, just like human trials.

Doggy drug trials in oncology have gained the most traction. (Just try corralling cats!) Veterinarians are quite supportive, because few cancer drugs are available for dogs. The trials provide access to sorely needed treatments as well as insight about cancer.

As an added benefit, man's best friend turns out to be a good model for testing cancer drugs that researchers are developing for humans. About 25% of pet dogs will suffer some form of cancer in their lifetime, and dog tumors often correlate well with human cancers. For example, Labrador retrievers, the most popular pet breed in the US, develop human-like lymphomas.

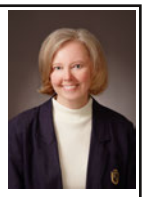
Because dog tumors emerge spontaneously (unlike lab-induced tumors in experimental mice), they are heterogeneous, like human tumors. The size and speed of growth of those "natural" tumors are also comparable between dogs and humans. And unlike mice, dogs and humans share a majority of their genetic material, allowing researchers to use data from a dog's cancer gene to extrapolate to the analogous gene in humans.

Drug testing in mouse models, however, is unlikely to disappear in near-future, in spite of the fact that just about 10% of the investigational agents that show great activity in tumor-bearing mice will show similar activity in human cancers. As one researcher put it, "If you have cancer and you're a mouse, we can take good care of you." On the other hand, the data generated from dog trials provide relevant data for treating humans, as well as helping the lab Labs.

The National Cancer Institute has launched the Comparative Oncology Trials Consortium, a network of 20 veterinary hospitals with oncology expertise, to recruit pet dogs diagnosed with specific types of cancer. The protocols and procedures for the four-legged patients mimic human chemotherapy trials. The animals are given well-established treatments, in addition to the investigational drug, just like human oncology patients.

And the care at those vet hospitals is excellent. According to one distinguished veterinarian, "The joke is that oncologists treat their patients like dogs, and we treat our patients like people." Data collection may be a challenge, though. How do you craft PRO (patient-reported outcomes) forms for a dog? Perhaps, Fido will get his own App.

Although, as expected, the NCI's dog trials are closely regulated, there is better efficiency: vet investigators can run ten trials for the cost of one human trial. Not surprisingly, all of this has piqued the interest of drug companies. The doggy data will speed drug development, predict human efficacy more accurately, and provide stronger justification for the pivotal and costly Phase III clinical trials. Hopefully, that translates into a more certain and faster drug approval. So, someday, a drug company's NDA may be based on trials that saved Scooby Doo and his friends, as well as their owners.



REBECCA J ANDERSON, PhD, is a freelance medical writer and the author of two books, *Nevirapine and the Quest to End Pediatric AIDS* and *Career Opportunities in Clinical Drug Research*. Prior to medical writing, Dr. Anderson managed research and development projects for twenty-five years in the pharmaceutical/biotech industry. She holds a Ph.D. in pharmacology from Georgetown University. She lives in Southern California, and when she is not writing, she absorbs the sights and sounds of the West Coast's rich culture and heritage. She can be reached at rebeccanderson@msn.com.

News and Updates from the FDA

Kokil Tandon, MBBS, MBA

Member, AMWA Pacific Southwest Chapter

The agency continued its trend of granting approval to a number of novel treatments in December 2015. The indications for these are described below.

Kanuma
The FDA approved the first treatment for adult and pediatric patients with a rare enzyme disorder called lysosomal acid lipase (LAL) deficiency (or Wolman disease - which is the very severe infant form or cholesteryl ester storage disease [CESD]- which is the milder later onset form). Kanuma (Alexion Pharmaceuticals Inc.) is indicated for this inherited disorder, in which patients have little or no LAL enzyme activity. This causes a build-up of fats within the cells of various tissues, which subsequently can lead to liver and cardiovascular disease and other complications. Kanuma, provides a recombinant form of human lysosomal acid lipase (rhLAL) protein that functions in place of the missing, partially active or inactive LAL protein in the patient. Kanuma received a breakthrough therapy designation, as it is the first and only treatment for Wolman disease. The FDA granted Kanuma orphan drug designation because it treats a disease affecting fewer than 200,000 patients in the United States. The Kanuma application was also granted a priority review, which is granted to drug applications that show a significant improvement in safety or effectiveness in the treatment of a serious condition The manufacturer of Kanuma was granted a rare pediatric disease priority review voucher– a provision that encourages development of new drugs and biologics for the prevention and treatment of rare pediatric diseases.

Vonvendi, von Willebrand factor (Recombinant)
The FDA approved the first recombinant von Willebrand factor for use in adults 18 years of age and older who have von Willebrand disease (VWD). VWD is the most common inherited bleeding disorder, affecting approximately 1 percent of the U.S. population. Vonvendi (Baxalta U.S., Inc.) is indicated for the on-demand treatment and control of bleeding episodes in VWD patients. Vonvendi was granted orphan product designation.

Vistogard
Vistogard (Wellstat Therapeutics Corporation) was approved for the emergency treatment of adults and children who receive an overdose of the cancer treatment fluorouracil or capecitabine, or who develop certain severe or life-threatening toxicities within four days of receiving these treatments. While an overdose of fluorouracil or capecitabine is rare, the effects are serious and may be fatal. Vistogard, taken orally, blocks cell damage and cell death caused by fluorouracil chemotherapy. The safety and efficacy of Vistogard initiated more than 96 hours following the end of chemotherapy have not been established. The FDA granted Vistogard orphan drug designation, priority review and fast track designations.

Bridion
FDA approved the first drug in a new class of medications that enables medical personnel to reverse the effects of neuromuscular blocking drugs and restore spontaneous breathing after surgery. Bridion (Merck Sharp and Dohme Corp., a subsidiary of Merck and Company, Inc.) injection is indicated to reverse the effects of neuromuscular blockade induced by rocuronium bromide and vecuronium bromide. These drugs may be used during tracheal intubation/ventilation during surgery/to prevent patients from moving during surgery while they are receiving general anesthesia

Voluntary recalls were issued by a number of companies at the end of last year, as well as at the beginning of this year. These include: Glades Drugs, Lipo Escultura Corp., Lucy's Weight Loss System, Reesna Inc., Baxter International Inc., SmartLipo365 of Dallas, TX, BeeXtreme LLC, PharMEDium Services, LLC, R Thomas Marketing LLC in conjunction With Just Enhance LLC, Abbott's Compounding Pharmacy, and Master Herbs, Inc.

A few advisory committee meetings, as well as workshops have been scheduled for February.

Selected FDA Announcements

Date	Announcement
11-25-15	FDA announced the voluntary nationwide recall issued by Glades Drugs of compounded multivitamins. The recall was issued due to the presence of high amounts of Vitamin D3 (Cholecalciferol) in the capsules. Consumption of the multivitamins could result in vitamin D toxicity, which may be severe and cause life-threatening outcomes if left untreated.[1]

12-03-15	Lipo Escultura Corp. of Brooklyn, NY dba JAT Productos Naturales Corp., and JAT Natural Products Corp. issued a voluntary nationwide recall of all Lipo Escultura within expiry. The weight loss dietary supplement was found to contain two potentially undeclared harmful ingredients--sibutramine and diclofenac. Sibutramine was removed from the market for safety reasons and is known to substantially increase blood pressure and/or pulse rate and may present a significant risk for patients with a history of coronary artery disease, congestive heart failure, arrhythmias or stroke. Diclofenac may cause increased risk of cardiovascular events and serious gastrointestinal damage.[2]
12-09-15	Lucy's Weight Loss System, issued a voluntary nationwide recall of all lots of Pink Bikini White powder Capsules, 30 white (750MG per capsule). Pink Bikini dietary supplement has been found positive for diclofenac after FDA sampling and testing. This undeclared ingredient makes this product an unapproved new drug for which safety and efficacy have not been established. Diclofenac can increase the risk of fatal heart attack or stroke, especially on long term use/with high doses/ with pre-existing heart disease. It can also harm the unborn baby if taken by a pregnant consumer in the last trimester.[3]
12-11-15	Reesna Inc. issued a voluntary nationwide recall of all lots of the Fuel Up Plus and Fuel Up High Octane distributed in August 2015 . Fuel Up is marketed as dietary supplement sexual enhancer for men. The recall was issued as the supplements contain undeclared hydroxythiohomosildenafil, an analogue of sildenafil. Sildenafil is an FDA-approved drug for the treatment of male Erectile Dysfunction (ED), making Fuel Up an unapproved drug. Hydroxythiohomosildenafil has a similar structure to sildenafil and is expected to possess a similar pharmacological and adverse event profile.[4]
12-18-15	Baxter International Inc. issued a voluntary recall of two lots of intravenous solutions due to the potential presence of particulate matter (i.e. an insect). The recalled solutions included lot no. C980227 of 0.9% Sodium Chloride Injection, USP, 250 mL VIAFLEX Plastic Container; and lot no. C985150 of 70% Dextrose Injection (2000 mL) USP. The lots being recalled were distributed to customers and distributors in the United States between June 6, 2015 and December 16, 2015.[5]
12-18-15	SmartLipo365 of Dallas, TX issued a voluntary nationwide recall of all lots of the dietary supplement Smart Lipo (800, 900, 950 mg) capsules. FDA's analysis found the Smart Lipo products to contain undeclared sibutramine, desmethylsibutramine, and phenolphthalein. These undeclared ingredients make these products unapproved new drugs for which safety and efficacy have not been established. These products may also interact with other medications taken by a consumer in life-threatening ways.[6]
12-23-15	BeeXtreme LLC issued a recall of all lots of its dietary supplements La' Trim Plus, Jenesis and Oasis. The FDA found undeclared sibutramine and phenolphthalein in these supplements. Sibutramine is an appetite suppressant that was withdrawn from the U.S. market in October 2010. Phenolphthalein is an ingredient previously used in over-the-counter laxatives, but because of concerns of carcinogenicity, it is not currently approved for marketing in the United States. Both these ingredients pose significant health hazards.[7]
12-31-15	PharMEDium Services, LLC issued a voluntary nationwide recall of 29 lots of 4mg Norepinephrine Bitartrate (16mcg/mL) added to 0.9% Sodium Chloride in 250mL Viaflex Bag and 3 lots of 8mg Norepinephrine Bitartrate (32mcg/mL) added to 0.9% Sodium Chloride in 250mL Viaflex Bag, distributed to hospital customers. This recall was issued due to complaints of product discoloration, which is indicative of degradation and could result in decreased potency due to oxidation of Norepinephrine Bitartrate.[8]
01-06-16	U.S. Marshals, at the agency's request, seized nearly 90,000 bottles of dietary supplement RelaKzpro, worth more than $400,000. RelaKzpro is manufactured for and held by Dordoniz Natural Products LLC, in South Beloit, Illinois. It is labeled as containing kratom, which has been identified as a botanical substance, indicated to have narcotic and stimulant-like effects. Its consumption can lead to several health impacts, such as respiratory depression, vomiting, nervousness, weight loss and constipation. In February 2014, the FDA issued an import alert allowing U.S. officials to detain imported dietary supplements and bulk dietary ingredients that are, or contain kratom without physical examination. A complaint was filed by the U.S. Department of Justice, on behalf of the FDA, in the U.S. District Court for the Northern District of Illinois, alleging that kratom is a new dietary ingredient for which there is inadequate information to substantiate that it does not present a significant or unreasonable risk of illness or injury; thus, dietary supplements containing kratom are adulterated under the Federal Food, Drug and Cosmetic Act (FD&C Act). The FDA is warning consumers not to use any products labeled as containing kratom. Further, they should report any related adverse events to the MedWatch program.[9]

01-09-16	R Thomas Marketing LLC in conjunction With Just Enhance LLC, issued a voluntary nationwide recall of the following products marketed as dietary supplements for male sexual enhancement: Black Ant, Herb Viagra, Real Skill, Weekend Prince, African Black Ant and Stree Overlord along with multiple other products. These were tested by the FDA and found to contain Sildenafil, which is not listed on the product labels. Since Sildenafil is the active ingredient in an FDA-approved drug for ED, these dietary supplements are unapproved. Sildenafil may interact with nitrates found in some prescription drugs such as nitroglycerin and may lower blood pressure to dangerous levels. Also it may cause side effects, such as headaches and flushing.[10]
01-11-16	A U.S. District Judge entered a consent decree of permanent injunction between the United States and Downing Labs LLC, of Dallas, Texas, the company's co-owners, and pharmacist-in-charge. The action was brought by the U.S. Department of Justice, on behalf of the FDA. According to the complaint filed with the decree, Downing Labs (formerly known as NuVision Pharmacy) manufactured and distributed purportedly sterile drug products that were adulterated because the drugs were made under insanitary conditions and in violation of current good manufacturing practice requirements under the FD&C Act. The decree prohibits Downing Labs and its owners from manufacturing, holding or distributing drugs until they comply with the FD&C Act and its regulations, in addition to other requirements. Most recently, Downing Labs conducted a voluntary nationwide recall of its purportedly sterile drug products due to a lack of sterility assurance and ceased sterile operations, due to serious deficiencies identified by the FDA during an inspection ending in October 2015. The deficiencies included microbial contamination of injectable drug products, inadequate cleaning and sanitization of sterile processing areas, and inadequate sterile practices. FDA investigators also determined that Downing Labs distributed drug products that failed sterility testing.[11]
01-16-16	Abbott's Compounding Pharmacy issued a voluntary recall of all lots of unexpired sterile human and animal compounded products due to lack of sterility assurance. These include injectable medications, sterile solutions, eye drops, and eye ointments. This recall impacts all sterile products distributed between 01/01/2015 and 01/14/2016, to patients, physician offices and clinics, and veterinarians within California.[12]
01-20-16	Master Herbs, Inc. issued a voluntary nationwide recall of all lots of the cough syrup called Licorice Coughing Liquid in 100 ml bottles. It was recalled due to the presence of Morphine, which is an opioid, and is not declared on the label. Thus, consumers using this product may not be aware they are ingesting morphine, which can lead to life-threatening respiratory depression and death, as well as severe allergic reactions in hypersensitive patients. In addition young children with a respiratory illness are vulnerable to respiratory depression from opioids and should not be exposed to morphine in any event.[13]

Selected FDA Approvals

Drug	Indication	Company
Opdivo®	Metastatic renal call carcinoma, previously treated with anti-angiogenic therapy[14]	Bristol-Myers Squibb
Portrazza™	Metastatic squamous non-small cell lung cancer (NSCLC), in combination with gemcitabine and cisplatin (in patients who have not previously received medication specifically for treating their advanced lung cancer)[15]	Eli Lilly and Company
Empliciti™ (orphan drug)	Multiple myeloma, in combination with Revlimid and dexamethasone, in previously treated with one to three prior medications[16]	Bristol-Myers Squibb
Alecensa® (orphan drug)	Metastatic anaplastic lymphoma kinase(ALK)-positive NSCLC patients who worsened after/ were intolerant to Xalkori[17]	Genentech
Basaglar®	Type 1 diabetes mellitus and Type 2 diabetes mellitus[18]	Eli Lilly and Company
Uptravi® (orphan drug)	Pulmonary arterial hypertension[19]	Actelion Pharmaceuticals US, Inc.
Zurampic®	Hyperuricemia, associated with gout, in combination with a xanthine oxidase inhibitor[20]	AstraZeneca Pharmaceuticals LP

February 2016 Advisory Committee Meetings

Date	Committee
02-3-16	Meeting of the Psychopharmacologic Drugs Advisory Committee Meeting Announcement – Discussion of cognitive dysfunction in major depressive disorder and discussion of the NDA 204447/supplemental NDA 006 submitted by Takeda Development Center Americas, Inc.[20]
12-9-16	Arthritis Advisory Committee Meeting Announcement – Discussion of the BLA submitted by Celltrion, Inc.[22]

February 2016 Conferences, Workshops and Public Meetings

Date	Title
02/3/16	8th Annual Sentinel Initiative Public Workshop – convened by Duke-Margolis Center for Health Policy, under cooperative agreement with FDA.[23]
02/23-25/16	Arthritis Foundation & Food and Drug Administration Accelerating OA Clinical Trials Workshop.[24]

WEBLINKS

- For additional information on approvals, including labeling revisions, tentative approvals, efficacy supplements with supporting clinical data, manufacturing changes or additions, or chemistry; new strength, see http://www.fda.gov/NewsEvents/Newsroom/default.htm
- For additional information on recalls, market withdrawals, and safety alerts, see http://www.fda.gov/Safety/Recalls/default.htm
- For information on current drug shortages, see http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm
- For information on drugs to be discontinued, see http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm
- For Orange Book drug product list additions or deletions, see http://www.fda.gov/Drugs/InformationOnDrugs/ucm086229.htm

[1]http://www.fda.gov/Safety/Recalls/ucm474636.htm
[2]http://www.fda.gov/Safety/Recalls/ucm475550.htm
[3]http://www.fda.gov/Safety/Recalls/ucm476494.htm
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[14]http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm473971.htm
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[16]http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm474684.htm
[17]http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm476926.htm
[18]http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm477734.htm
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[21]http://www.fda.gov/AdvisoryCommittees/Calendar/ucm475312.htm
[22]http://www.fda.gov/AdvisoryCommittees/Calendar/ucm481969.htm
[23]http://www.fda.gov/Safety/FDAsSentinelInitiative/ucm149341.htm
[24]http://www.fda.gov/Drugs/NewsEvents/ucm479200.htm

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Ask APRIL: Resolve to Never Tidy Again

By April Reynolds, MS, ELS, AMWA Pacific Southwest Chapter Member

With the New Year always comes talk of resolutions. Maybe one of them could be getting your home in order so your life will follow. Marie Kondo's book on organizing tells us how.

According to Google Trends, interest in Marie Kondo and her *New York Times* bestselling book on organizing entitled *The Life-Changing Magic of Tidying Up* reached an all-time high this January,[1] likely due to an increased interest in de-cluttering for the New Year. The book has permeated popular culture, and Kondo, a former Shinto shrine attendant maiden turned cleaning consultant, boasts a hefty clientele and a months-long waitlist for her organizing services. Her book promises that you'll never have to tidy your home again after following her eponymous KonMari Method.

The method starts with discarding, followed by organizing your living space thoroughly and completely in one session. Kondo says it should take about 6 months to properly go through an entire house. After sorting and discarding, everything that remains should be given its own place. Once you are done using something, you simply put it back where it belongs and you'll never have to tidy again.

The method and me

The book was recommended to me by my Feng shui consultant, in part, because I have too many clothes but also because it's very closely aligned with Feng shui. The idea is to create a living space, and ultimately a life, that reflects your best self. Don't hold on to something out of obligation or the assumption that you'll use it in the future. Live happily and joyfully in the present.

I revisited the book recently after renovating my bedroom to include a much larger closet. But even with the new space, there is still not enough room to house all of my clothes. I struggled with deciding what to keep and what to donate because collecting clothes has been a pastime of mine for many years.

Some say to get rid of clothes you haven't worn in [insert amount of time, ie, 6 months or 1 year]. That doesn't work for me because I often bring things out of hiding 5, 6, or even 7 years later. And because I tend to buy timeless pieces, this arbitrary time limit doesn't seem applicable.

Another idea is to construct a custom closet interior, with storage so ample I'll probably forget what all I have. Kondo says storage is for hoarders, and I have to agree. I can envision myself buying the same thing more than once simply because I can't see it.

Ask yourself: does this bring me joy?

The selection criterion for keeping or discarding an item, according to the KonMari Method, is to ask yourself if an item brings you joy. This means you must handle every object under consideration. The goal is to feel if an item continues to spark a sense of joy or if it has served its purpose in your life and needs to move on. But focus on the positive: think about what you want to keep instead of what you should discard.

I like this idea of respect. I put a lot of time and money into building a wardrobe, so to just discard something on the basis of an arbitrary time limit seems a bit callous. And once I'm done filling my new space with only those items that make my happy, I'll have a closet full of my favorite things!

Tidy by category not by type

The book has some practical advice on how to approach organization, like tidying by category instead of location, meaning going through all your shirts instead of going through your house room by room. This is because people often store the same types of items in different locations.

The book warns against starting with mementos, as they elicit too emotional of a response. Instead, beginners should build confidence in their decision-making skills by adapting a sequence that includes clothes first, then books and papers, followed lastly by mementos. Kondo gives more explicit instructions on tidying that include practical advice on folding, arranging clothes in a way that energizes the closet, and drawer organization techniques.

Psychology plays a role

At first, you may think Kondo is over the top. She comes across as obsessed with organization from a very young age. And she credits her services with discarding over a million items, including one client's collection of 20,000 unused cotton swabs. But the message becomes softer and more palatable as you get deeper into her thought process on discarding, joy, and respect.

An article on Marie Kondo in **The Atlantic** explores underlying themes that cause us to buy things we don't need, keep things we don't use, and continue to perpetuate this cycle.[2] As resistant as we may be

to her message of discarding, Kondo insists that we must change our thinking in order to change our habits and, ultimately, our lives.

Care for your things so they can do the same for you

Do you thank your bag for carrying your things all day? Or your house for giving you shelter and warmth? Do you smile when you open your closet? According to Kondo, you should.

In this New Year, I'd like to be more mindful of how I spend my time and money. I invite you to join me in considering the following from Marie Kondo: "the question of what you want to own is actually the question of how you want to live your life."

For more, follow Marie Kondo's blog at:
http://tidyingup.com/

References:
1. https://goo.gl/rQJxcg
2. http://goo.gl/41DzJf

APRIL REYNOLDS, MS, ELS, is a medical writer & editor and the president of Write/Correct, Inc. She has published works on topics that range from jeans (for fashion magazines) to genes (for medical publications). She lives in San Diego with her husband and son.

Medical writing's own fashion experimenter and amateur decorator answers your style questions.

Email your questions to: AskAprilatAMWA@gmail.com.

Precision Medicine Initiative and Communicating Genetic Testing Results

Kokil Tandon, MBBS, MBA

Member, AMWA Pacific Southwest Chapter

The Precision Medicine Initiative (PMI) was launched by President Obama in January 2015. It enables providers to develop customized treatment and prevention strategies for patients, based on individual differences in their genes, environments, and lifestyles. This initiative was launched with a $215 million investment in the President's 2016 budget and may involve the analysis of genetic information gathered through Next Generation Sequencing (NGS) technologies.[1] Thus, as part of PMI, the FDA was charged with developing a new approach to evaluate NGS technologies, so that accurate and innovative tests can be developed to generate knowledge about genetic changes relevant to patient care.

What is NGS?

NGS is a cutting-edge process that determines the DNA sequence of an individual by assessing multiple genes in a single assay. It can be applied to a subset of key genes or the entire genetic code. This method offers several advantages over traditional genetic tests in terms of providing highly sensitive and accurate results with a rapid turnaround. Also, NGS is more economical and eliminates the need to order multiple tests, as it is a multi gene approach.

A noteworthy example of the diverse utilization of data garnered from NGS-based tests can be seen in the practice of oncology. For instance, oncologists are increasingly using these tests to gather information about the factors which underlie cancer progression. Additionally, they are beginning to use results of NGS-based diagnostics to tailor the choice of drugs or drug combinations for a specific patient.[2]

A number of biotechnology companies have been working on developing and refining NGS based non-invasive tests for cancer screening and real-time detection.

It is envisioned that these tests will lead to earlier diagnosis, improved survival rates, and better quality of life for cancer patients.[3]

FDA Workshop on Communicating Genetic Testing Results

On January 14, 2016, the FDA announced that it will conduct a public workshop entitled "Patient and Medical Professional Perspectives on the Return of Genetic Test Results", on March 2, 2016.[4] The meeting notice in the Federal Register specifically cites the PMI.

What is the purpose of this workshop?

Overall, NGS based tests have allowed the availability of a multitude of patient and disease related data. However, given the copious amounts of data generated, physicians are sometimes presented with information that may be difficult to analyze on the basis on current scientific and medical knowledge. Further, not all of the data generated may be helpful to patients in terms of enhancing their understanding of a particular disease state or translate into viable preventive or treatment options. Thus, the FDA is planning to solicit input from patients and healthcare professionals, via the aforementioned workshop, about how the results of genetic tests can be conveyed to them in a manner that is meaningful and can aid medical decision-making. Various topics will be discussed by speakers including the different uses of genetic testing; how to present the result of genetic tests effectively; patients' preferences to receive results supported by limited/conflicting evidence/ if no medical action can be taken; providers' preferences to receive results supported by limited/conflicting evidence; which information can be included/excluded from test reports and how to present information so it can be easily integrated into clinical care by providers.

Electronic or written comments will be accepted until March 31, 2016.[4]

Sources:

[1]https://www.whitehouse.gov/the-press-office/2015/01/30/fact-sheet-president-obama-s-precision-medicine-initiative

[2]https://www.illumina.com/content/dam/illumina-marketing/documents/products/other/primer-ngs-oncology.pdf

[3]http://www.technologyreview.com/news/545326/illuminas-bid-to-beat-cancer-with-dna-tests/

[4]https://www.federalregister.gov/articles/2016/01/14/2016-00540/patient-and-medical-professional-perspectives-on-the-return-of-genetic-test-results-and

Meeting Report

AMWA Kicks Off the New Year with Leadership and Mentoring

Eileen Lai-Hoshino, MS, MPH, MBA

Member, AMWA Pacific Southwest Chapter

On January 16, 2016, AMWA's Pacific Southwest Chapter convened with a presentation and luncheon held at Cal State Northridge to usher in the New Year and new leadership. The luncheon began with Donna Simcoe handing over the AMWA President's gavel to newly elected President, Susan Vintilla-Friedman, for the next two-year term of chapter leadership. Ms. Simcoe, who helmed the Southwest Chapter from 2014-2015, was instrumental in bringing new types of events such as the popular, monthly teleconference call for AMWA members to connect with one another, share ideas and discuss relevant industry issues. The audience members applauded Ms. Simcoe for her dedication and the many contributions under her leadership.

Following the inauguration of the newly elected president, Michele Vivirito presented an informative lecture on how to successfully mentor junior medical writers. Drawing on her 30 plus years at Amgen as a professional medical writer and mentor, Ms. Vivirto discussed what the essential qualities of a good mentor should be, such as compassion, candor, and confidentiality. She also emphasized the differences between being a mentor (versus being a trainer) and that developing a productive mentor/mentee relationship should be based on mutual respect and trust.

Ms. Vivirto also introduced several useful tools and models such as the SMART goals (Specific, Measurable, Achievable, Relevant, Time-bound) and CMO model (Competency, Motivation, Opportunity) to help potential mentors guide their mentees through career development issues. According to Ms. Vivirto, good communication is not only imperative to successful medical writing, but also to successful mentoring. She recommended the use of personality assessment tools such as the Myers-Briggs temperament sorter into effectively develop communication styles based on personality types. The presentation elicited an informative discussion between the audience members, which included both experienced industry writers and newly aspiring medical writers. All in all, the presentation on mentoring was a wonderful introduction to the New Year and new leaderships.

EILEEN LAI-HOSHINO, MS, MPH, MBA is an experienced healthcare professional with experience in both the medical and business fields. She has experience working in the clinical environment as a licensed medical professional (PA-C) and management consultant in strategic planning, marketing, performance management and training design. She holds a Masters of Medical Science, an MBA in health care marketing strategy and MPH in healthcare policy and economics.
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AMWA Event: Successful Mentoring of Medical Writers (Pictures)

Pictures by Elise Sudbeck and Eileen Lai-Hoshino

Clockwise from top left: (1) Donna and Susan, (2) Michele V, (3) Michele, Susan, Lamia, (4) meeting participants, (5) Susan E, Ajay, Aaron, (6) Jenny, Jacki, Jim H. Read the meeting report by Eileen Lai-Hoshino on page 20.

Event: Successful Mentoring of Medical Writers
Speaker: Michele Vivirito is a medical writing consultant with more than 30 years of experience in the pharmaceutical industry. She has mentored many medical writers, including newly hired writers and experienced writers taking on new responsibilities. She has also developed programs to train mentors.

Date: Saturday, January 16, 2016
Location: California State University Northridge, Orange Grove Bistro, 18111 Nordhoff Street, Northridge, CA 91330-8271

Medical Writing as a Career;
A Panel Discussion at Sanford Burnham Prebys Medical Discovery Institute

By Asoka Banno, PhD

Outreach Coordinator for AMWA Pacific Southwest Chapter Member

CAREER

On January 27, 2016, in collaboration with Sanford Burnham Prebys Medical Discovery Institute, AMWA Pacific Southwest Chapter hosted a panel discussion on career in medical writing for the audience of approximately 15 postdocs at the institute. Three of our chapter members, Amy Lindsay, Noelle Demas, and Robin Weaver kindly volunteered to participate as panelists.

Following brief introductions about their career paths, the panelists introduced medical writing as a profession and described its nature and diversity. We then opened up the floor for questions from the audience, during which many interesting topics were discussed. The panelists agreed that the maintenance of data/science integrity is one of the key responsibilities of a medical writer, whether it is peer-to-peer communication or regulatory writing. Traits that the panelists thought are necessary to be a successful medical writer included adaptability and flexibility, project management and leadership skills, attention to detail, ability to work as a team and independently, and willingness to learn, in addition to data analysis and logic building skills and mastery of writing and oral communication. The panelists also noted that some of the ways that individuals can show their commitment to the field and to distinguish themselves from others with similar background are to obtain formal training in medical writing, such as through AMWA, UCSD Extension, and other local or online-based programs, and to get involved with local professional societies.

Another session about career in medical writing, with Amy Lindsay, Noelle Demas, and Laura Alper, has been planned for February 22 at University of California, San Diego.

ASOKA BANNO, PhD, is currently a freelance medical writer based in San Diego. Her current projects include clinical overviews on a variety of human diseases and research manuscripts based on clinical study reports. Before embarking on medical writer career, she was an oncology researcher at UC San Diego and Mount Sinai School of Medicine. Her research projects included mechanism of epithelial-mesenchymal transition, a key phenomenon that takes place during cancer metastasis, the role of R-Ras in tumor metastasis of glioblastoma and the role of BCR-ABL in myeloid leukemic stem cells. She earned her PhD from UC San Diego. She is fluent in English and Japanese. She can be reached at asoka828@gmail.com or via LinkedIn is at https://www.linkedin.com/in/asokabanno

Chapter Upcoming Events' Calendar

AMWA Pacific Southwest Chapter lunch (monthly) teleconference
Occurs First Friday of the month, 12-1 pm Pacific time
Dial in number: 706-913-1155
Participant code: 0204157# (or from your iPhone: 706-913-1155,0204157#)
Discussion topic for **Feb 5, 2016 - Dealing with a difficult work environment**

February 9, 2016 ,Tuesday. **Orange County Happy Hour** at 5:30 PM.
Where: El Torito in Tustin, 17420 East 17th Street, Tustin, CA 92780
Everyone is invited to join for an evening of networking with AMWA colleagues.

February 22, 2016 – UCSD campus. **Medical writing workshop**. *Details to be announced soon via chapter email blast*.

While at TIPPA meeting, join for a **happy hour** hosted by our chapter on Monday, **February 29th from 6 pm to 7:30 pm** at The Cays Lounge in Loews Coronado Bay Resort. (Pay for your own drinks). All are welcome. Address: 4000 Coronado Bay Road, San Diego, California, 92118. Phone: 619-424-4000
https://www.loewshotels.com/coronado-bay-resort/dining/lounge

March 12, 2016 – AMWA presentation at CareFusion. Marilyn Allison will speak on **Career Transitions**.

April 16,2016 – **AMWA Pacific Coast Conference**
Where: Park Central San Francisco, A Starwood Hotel, 50 Third Street, San Francisco, CA 94103. Visit http://amwancal.org/ for more information.

April 29, 2016 (tentative) – Webinar presentation by Thomas Purcell on **Project Management for Medical Writers**.

Medical Writing Open Positions

Compiled By: **Sharyn Batey, PharmD, MSPH**

Employment Coordinator, AMWA Pacific Southwest Chapter

Medical Writer, Senior Manager
Avanir Pharmaceuticals, Inc, Aliso Viejo, CA
http://job-openings.monster.com/monster/c7b9c55e-73ec-4ec5-b75d-1cce19f67ac7?mescoid=2700440001001&jobPosition=3#

Medical Writer - Promotional Activities
Arbor Scientia, Carlsbad, CA
http://jobview.monster.com/Medical-Writer-Promotional-Activities-Job-Carlsbad-CA-US-162248413.aspx?mescoid=2700440001001&jobPosition=10

Medical Writer – Continuing Medical Education (CME)
Neuroscience Education Institute, Carlsbad, CA
http://jobview.monster.com/Medical-Writer-%E2%80%93-Continuing-Medical-Education-CME-Job-Carlsbad-CA-US-162924785.aspx?mescoid=2700440001001&jobPosition=11

Medical Writer
Medtronic Inc., Goleta, CA
http://job-openings.monster.com/monster/5938cbbe-2032-4b6f-9e2e-0d6fd14ce02e?mescoid=2700440001001&jobPosition=7#

Medical Writer
Recruiting for Undisclosed Company
ALKU, Los Angeles, CA
http://job-openings.monster.com/monster/41bdacc2-d985-4dde-bf7c-23947a917e10?mescoid=2700440001001&jobPosition=9#

Senior Medical Content Editor
Cline Davis & Mann, Inc., Los Angeles, CA
http://job-openings.monster.com/monster/ac456d70-3416-435b-9b9c-4462860be4c6?mescoid=2700439001001&jobPosition=4#

Technical Writer/Editor (Pharmaceutical/Device)
Recruiting for Undisclosed Company
ConsignMed, Santa Ana, CA
http://jobview.monster.com/Technical-Writer-Editor-Job-Santa-Ana-CA-US-161846084.aspx?mescoid=2700440001001&jobPosition=16

Senior Medical Writer (Medical Communications)
Recruiting for Undisclosed Company in San Diego Area
Liberty Jobs, San Diego, CA
http://job-openings.monster.com/monster/12bcfad0-d23b-4b0e-b3d9-5a0bb79b2c20?mescoid=2700440001001&jobPosition=2

Medical Communications Manager
Recruiting for position at Amgen (2 year contract)
Hart Employment Services, Thousand Oak, CA
http://hartjobs.com/careers/?cjobid=HS938238527&rpid=16202

Principal Scientific Communications Manager
Boston Scientific, Valencia, CA
http://job-openings.monster.com/monster/75ac8e64-97e2-4e29-b54c-384626233089?mescoid=1100009001001&jobPosition=16#

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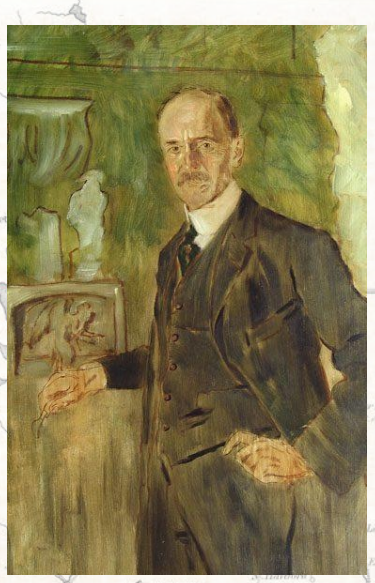
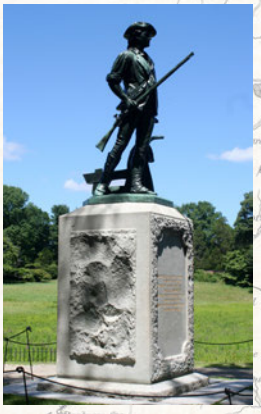
If you want to share job leads with the members of the Pacific Southwest Chapter, please contact Sharyn at employment-coordinator@amwa-pacsw.org.

Presidents, New Hampshire and Daniel Chester French



February is the month of All Things Presidents: Lincoln and Washington's birthdays, and New Hampshire giving us the first primary contest which will lead us to the President's election in November. New Hampshire also is the birthplace of a famous sculptor and artist, Daniel Chester French (1850-1931) who designed the Lincoln statue for the Lincoln Memorial in Washington, DC.



Daniel Chester French, born in Exeter, New Hampshire, studied anatomy and drawing, and spent a year studying art in Italy. His first commissioned work and source of acclaim was the Minute Man statue for the town of Concord, Massachusetts, which was unveiled on April 19, 1875, on the centenary of the battle of Lexington and Concord.

Over his career, he designed numerous public monuments and statues. With H Augustus Lukeman, he also designed the Pulitzer Prize medal in 1917 – French designed the picture of Benjamin Franklin on one side, and for the other side of the medal, Lukeman came up with the design of a printing press and wordings, "For the disinterested and meritorious public service rendered by an American newspaper during the year."

French was the founding member of US Commission of Fine Arts and also of National Sculpture Society, fellow of American Academy of Arts and Sciences, and a member of several other major organizations. In 1940, he was one of five artists to be honored on a US First-Class stamp. He died in Stockbridge, Massachusetts, and was buried in Sleepy Hollow Cemetery in Concord, the town where he started his career with the Minute Man statue.

— Editor

Sources: Wikipedia and Wikimedia